



U.S. DEPARTMENT OF COMMERCE

International Trade Administration

REQUEST FOR COMMENTS ON WORLD HEALTH ORGANIZATION PANDEMIC

INFLUENZA PREPAREDNESS FRAMEWORK

AGENCY: International Trade Administration, U.S. Department of Commerce

ACTION: Notice and Request for Comments

SUMMARY: The International Trade Administration invites submission of comments from the public and relevant industries on influenza surveillance and response, related to the implementation of the World Health Organization (WHO) Pandemic Influenza Preparedness Framework (PIP-FW) (http://apps.who.int/gb/ebwha/pdf_files/WHA64/A64_8-en.pdf).

Comments will be used to support the five-year review of the WHO PIP-FW in 2016.

DATES: Written comments must be submitted on or before October 7, 2015. Comments should be no more than 15 pages. Business-confidential information should be clearly identified as such.

ADDRESSES: Submissions should be made via the Internet at www.regulations.gov docket number ITA-2015-0003. For alternatives to on-line submissions please contact Jennifer Boger at (202) 482-3360. The public is strongly encouraged to file submissions electronically rather than by facsimile or mail.

FOR FURTHER INFORMATION CONTACT: Questions regarding the submission of comments should be directed to Jennifer Boger at (202) 482-3360, Jennifer.Boger@trade.gov, or

Bijou Mgbojikwe at (202) 482-1722, Bijou.Mgbojikwe@trade.gov.

SUPPLEMENTARY INFORMATION:

Background: In 2007, the Sixtieth World Health Assembly passed a resolution calling on the Director-General to convene an intergovernmental meeting to develop mechanisms to ensure the continued sharing of potential pandemic influenza viruses, and the fair and equitable sharing of benefits arising from such sample sharing. For four years, WHO member states met as an Intergovernmental Mechanism, as well as informally, to negotiate the Pandemic Influenza Preparedness Framework (PIP-FW). The PIP-FW came into effect on May 24, 2011 when it was unanimously adopted by the Sixty-fourth World Health Assembly.

The key goals of PIP are to improve and strengthen global influenza pandemic preparedness by:

1) Ensuring the global sharing of influenza viruses with human pandemic potential for continuous global monitoring and assessment of risks, and for the development of safe and effective countermeasures. The PIP-FW provides a transparent mechanism for sharing virus samples, based on two Standard Material Transfer Agreements (SMTAs) that specify the conditions for samples passed within and outside of the Global Influenza Surveillance and Response System (GISRS), and a traceability mechanism to monitor the movement of samples.

2) Increasing countries' access to vaccines and other pandemic related resources. Two innovative and complementary benefit-sharing mechanisms pool monetary and in-kind contributions from entities that use the GISRS to enhance pandemic influenza preparedness and response capacity for countries in need and at risk of pandemic influenza: the annual partnership

contribution and the SMTA-2.

At the core of the PIP-FW is a robust Global Influenza Surveillance and Response System (GISRS, previously called the Global Influenza Surveillance Network or GISN). Section 7.4.2 of the PIP-FW provides that: “The Framework and its Annexes will be reviewed by 2016 with a view to proposing revisions reflecting development as appropriate, to the World Health Assembly in 2017, through the Executive Board.” It is in anticipation of the 2016 review that the U.S. Department of Commerce seeks comments on the following points:

- 1) Experiences, best practices, opportunities, and challenges in advancing the PIP-FW over the past five years.
- 2) Experiences relating to the status and process of concluding Standard Material Transfer Agreements (SMTA2).
- 3) Use of partnership contributions and WHO efforts to strengthen the GISRS and overall global preparedness and response capability/capacity.
- 4) How changing technology has impacted or has the ability to impact the existing PIP-FW.
- 5) Other matters related to prevention, planning and response whose resolution will be integral for the effective operation of a global influenza pandemic response.

The facts and information obtained from written submissions will be used to inform the participation of the U.S. Department of Commerce in the interagency process to prepare for United States participation for the five-year 2016 review of the PIP-FW. Upon receipt of the written submission, representatives from the U.S. Department of Commerce will consider them

and share them, as needed, with other interested U.S. Government agencies and departments engaging in the five-year review process.

The Department of Commerce invites comments from civil society organizations as well as pharmaceutical and medical technology industries and other interested members of the public on a number of issues regarding pandemic influenza preparedness and response. Entities making submissions may be contacted for further information or explanation and, in some cases, meetings with submitters may be requested.

Dated: September 3, 2015

Jennifer Boger

Health Team Director, Office of Health and Information Technologies

Billing Code: 3510-DR-P

[FR Doc. 2015-22730 Filed: 9/9/2015 08:45 am; Publication Date: 9/10/2015]